**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

AMERICAN ACADEMY OF PEDIATRICS, AMERICAN COLLEGE OF PHYSICIANS, INC., AMERICAN PUBLIC HEALTH ASSOCIATION, INFECTIOUS DISEASES SOCIETY OF AMERICA, MASSACHUSETTS PUBLIC HEALTH ASSOCIATION D/B/A MASSACHUSETTS PUBLIC HEALTH ALLIANCE, SOCIETY FOR MATERNAL-FETAL MEDICINE, THE MASSACHUSETTS CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS, JANE DOE 1, JANE DOE 2, and JANE DOE 3,

*Plaintiffs,*

vs.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JIM O'NEILL, in his official capacity as Acting Director of Centers for Disease Control and Prevention; CENTERS FOR DISEASE CONTROL AND PREVENTION; and DOES 1–50, inclusive,

*Defendants.*

Case No. 1:25-cv-11916

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE THIRD AMENDED COMPLAINT**

District Judge: Hon. Brian E. Murphy
Magistrate Judge: Hon. M. Page Kelley

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## I. INTRODUCTION

The federal immunization recommendation framework, which produces the evidence-based immunization schedules published on the website of the Centers for Disease Control and Prevention ("CDC"), is a structured, scientific, data-driven process that stakeholders in the vaccine ecosystem have relied on for decades as the nation's authoritative mechanism for evaluating and implementing vaccine safety, effectiveness, and population-level use. Under this framework, the Advisory Committee on Immunization Practices ("ACIP") conducts a systematic evidence review of vaccines using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) methodology and the Evidence-to-Recommendation ("EtR") framework.[1] CDC then publishes the scientific, evidence-based rationale for the ACIP's vaccine recommendations in the Morbidity and Mortality Weekly Report ("MMWR"). This process (hereafter, the "ACIP recommendation process" or "ACIP framework") creates a transparent and nationally uniform evidentiary foundation for the CDC immunization schedules that physicians, medical practices, hospitals, patients, insurers, public health organizations, medical societies, and legislatures have grown to trust through the years.[2] Indeed, trust in the ACIP-recommendation process *was* so great that Congress and state legislatures explicitly incorporated ACIP recommendations into many laws such as the Affordable Care Act, the Vaccines for Children Program, Medicare Part D, and state school entry immunization requirements. *See* Third Amended Complaint ("TAC"), ECF 139, ¶¶ 31-37.

Defendant Robert F. Kennedy, Jr., Secretary of the United States Department of Health and Human Services (the "Secretary"), however, is waging an undeclared war against this long-

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[1] *See* Grace Lee, et al., *Updated Framework for Development of Evidence-Based Recommendations by the Advisory Committee on Immunization Practices,* 67 MORBIDITY & MORTALITY WKLY. REP. 1271 (Nov. 16, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/pdfs/mm6745a4-H.pdf [https://perma.cc/BW7J-B48U].

[2] *Id.*

standing ACIP framework contrary to the United States' statutorily-mandated "goal of increasing rates of vaccination across all ages … to reduce and eliminate vaccine-preventable diseases." 42 U.S.C. § 245(a). Since taking office, the Secretary has repeatedly made statements and taken action that demonstrate that he is pursuing a policy to decrease access to vaccines and rates of vaccination and increase rates of vaccine skepticism, hesitancy, and denialism in the U.S. population writ large. *See, e.g.*, TAC, ¶¶ 38-43, 46-49, 51-58 (detailing the Secretary's actions to undermine trust in vaccines and his unlawful appointments to the ACIP). The Secretary has not, however, made a public pronouncement that explicitly states that these are his policy goals, but instead has made a myriad of ambiguous, inconsistent, or conflicting statements about what his vaccine policy is. On the other hand, one of his recent appointees to the ACIP, Robert Malone, recently stated publicly that "*[a]t the specific direction of the … Secretary*, major changes in public health and vaccine policies are being made by Secretary Kennedy's team with the assistance of the reconstituted and redirected ACIP. From ending universal COVID shots to uncovering manipulated RSV data, *the Secretary's team is reshaping the foundation of U.S. vaccine policy*."[3]

Assuming the truth of Malone's statement, all the Plaintiffs ask in this case is for the Secretary to be honest and transparent about his intentions—*i.e.*, *explain himself in good faith*. Plaintiffs are not, contrary to the assertion in Defendants' Motion to Dismiss ("MTD" or "ECF 145"), "requesting that the Court implement [Plaintiffs'] policy preferences." *See* ECF 145, p. 1. Instead, Plaintiffs ask three basic questions under the Administrative Procedure Act, 5 U.S.C. §§ 551, *et seq.* ("APA"): (i) are you changing United States policy on vaccines, (ii) are you following the proper procedure to do so, and (iii) if so, explain why. The APA requires the Secretary to provide "reasonable explanation" for a drastic change in vaccine policy. *See Dep't of Com. v. New*

[3] Robert Malone, *Malone News*, Substack, https://www.malone.news/ [https://perma.cc/8JC4-GQPX] (last visited Dec. 13, 2025) (emphasis added) (attached as Exhibit 1).

*York*, 588 U.S. 752, 785 (2019). If he fails to provide a reasonable explanation, then the actions challenged here must be set aside under the APA. Plaintiffs have stated plausible claims of violations of the APA, and the MTD should be denied in its entirety.[4]

## II. FACTUAL BACKGROUND

### A. Designation of the Covid-19 Vaccine as SCDM on the Childhood and Adult Immunization Schedules.

#### 1. The Directive's Change to the Childhood and Adult Schedules

On May 27, 2025, the Secretary posted a video on social media platform X announcing that he had instructed the CDC to remove from its schedules the recommendation that pregnant women and children receive the Covid-19 vaccine. *See* TAC, ¶ 6. That same day, a written Secretarial Directive dated May 19 (the "Directive") was released that ordered the CDC to remove the Covid-19 vaccine from both the childhood and adult immunization schedules. *Id.* ¶ 6, 62. These actions sent shock waves through the vaccine ecosystem. *Id*. Curiously, even though the video and Directive unequivocally instructed the CDC to "remove" the Covid-19 vaccine from both schedules, the Covid-19 vaccine on the CDC's childhood and adolescent immunization schedule ("childhood schedule") was shortly thereafter changed to a "Shared Clinical Decision Making" ("SCDM") designation, not removed. *Id*. ¶ 64. No explanation was given for why the instruction to remove the Covid-19 vaccine from the childhood schedule was not followed. *Id*. ¶ 6. The Covid-19 vaccine recommendation with respect to pregnant women, however, was removed from the adult immunization schedule ("adult schedule"), *i.e*., changed to "No Guidance/Not Applicable." *Id*.

#### 2. The ACIP's September 19 Vote that Changed the Adult Schedule

[4] Plaintiffs concurrently file with this Opposition the declarations of the individual party plaintiffs (Jane Does 1–3), the association plaintiffs, and members of those associations as Exhibits 2-39. These declarations provide further factual support for the harms alleged in the Third Amended Complaint and are incorporated into this Opposition in full.

On September 19, 2025, the Secretary's new ACIP voted that vaccination with the Covid-19 vaccine for individuals six months to 65 years of age should be "based on individual-based decision-making." *See id*. ¶ 7. This vote resulted in no change to the childhood schedule, because the Covid-19 vaccine was already designated as SCDM pursuant to the Directive. *Id*. ¶ 6. This vote, however, changed the adult schedule from a routine recommendation to a SCDM designation for Covid boosters. *Id*. ¶ 7. Before casting this vote, the ACIP did not apply the GRADE criteria or the EtR framework as prior ACIPs had done in the past when voting on the Covid-19 or any other vaccine. *See id*. ¶¶ 59–61. Nor did the CDC issue guidance on how to engage in SCDM discussions with patients as it had done in the four—and only four—times that the ACIP had previously voted to designate a vaccine as SCDM limited to very specific age groups. *See id*. ¶ 7; *see also* Ex. 17 (Goldman Decl.) ¶ 10.

**3. Harm To Plaintiffs Caused by Changes to Both Schedules**

Both the Directive, which resulted in the change of the Covid-19 vaccine to SCDM on the childhood schedule, and the ACIP's September 19 vote to change the routine recommendation of the Covid-19 vaccine to SCDM on the adult schedule, have harmed the individual Plaintiffs, physician members of the Plaintiff Organizations, and the Plaintiff Organizations.

**i. The Directive**

The Directive caused harm to the individual Plaintiffs. Both Jane Doe 1 and Jane Doe 2 were expecting their first child this past summer and wanted to get the Covid shot during the third trimester of pregnancy to protect the child during the first six months after birth; due to the confusion that the Directive created at pharmacies, they could not receive the vaccine despite repeated attempts. *See* TAC, ¶¶ 19, 20, 83, 84. Although both eventually were able to receive boosters before delivery, the stress and anxiety of becoming a first-time mother were exacerbated by the fear of not being able to receive a Covid booster that would protect their fetus and newborn

and by the aggravation of driving to and calling multiple pharmacies to ask if the pharmacy would administer to them what had previously been a routine vaccine for pregnant women. *Id*. The fear, anxiety, and aggravation manifested in loss of sleep, headaches, fatigue, and exacerbation of anxiety disorder, prenatal depression, clinically significant sleep disturbances, and teeth grinding. *Id*. Jane Doe 3's son suffered a panic attack at his second attempt to get a Covid booster before school started in the Fall after the pharmacist at the first attempt refused to give him the vaccine because of the Directive. *Id*. ¶ 21. The son's panic attack before the second attempt would not have happened but for the Directive. These are all cognizable injuries that occurred after the Directive was issued but before the ACIP vote on September 19.

Plaintiff Organizations were forced to divert resources to counter the confusion that the Directive created throughout the vaccine ecosystem. *Id*. ¶ 86. For example, over the summer, Plaintiff American Academy of Pediatrics ("AAP") diverted significant resources to guide its 67,000 members on the implications of the Directive, including updating guidance documents for pediatric practices, fielding additional calls and emails from AAP members seeking clarification about the implications of the Directive, holding webinars on navigating the implications of the Directive, developing a new policy statement "Recommendations for COVID-19 Vaccines in Infants, Children, and Adolescents" that was published online on August 19, and developing a new AAP immunization schedule. *See* Ex. 15 (Del Monte Decl.) ¶¶ 4–9.

Plaintiff American Public Health Association ("APHA"), too, was forced to divert substantial staff time and resources to work with public health administrators to reconcile the Secretary's Directive and the new CDC immunization schedule with the longstanding, evidence-based schedule that had previously guided Covid-19 vaccination practices and determined how APHA advised their communities. *See* Ex. 19 (Benjamin Decl.) ¶ 27. APHA member and Health

Officer for the Snohomish County Health Department in Washington state, Dr. James Lewis, has had to divert his attention from other duties to work on changing state and local laws to no longer defer to CDC guidance or ACIP recommendations because the "Directive and other actions by the Secretary … undermine trust in vaccines." *See* Ex. 21 (Lewis Decl.) ¶ 6.

The Directive's change to the childhood schedule harmed individual physician members of Plaintiff Organizations. For example, Dr. Molly O'Shea, who owns two pediatric practices in Michigan and is an AAP member, attested that, "[s]ince the Directive, fewer parents are getting their children vaccinated for anything, including Covid-19, than was the case before the Directive. *See* Ex. 38 (O'Shea Decl.) ¶ 11. The vaccine conversations are much longer and more difficult. The change in vaccine uptake and more time with each family is already resulting in financial harm to my practice that can be directly tied to the Directive because I typically am not able to bill for and therefore am not paid for the extra counseling time that the Directive has forced me to engage in. The Directive is making me provide extra counseling on the Covid-19 vaccine for free," which then cuts into her ability to see other patients. *See id*. ¶ 11.

Dr. Mary-Cassie Shaw, a pediatrician in North Carolina and AAP member, has seen families disengage with the healthcare system "because of their mistrust of the COVID-19 and other vaccines. The Directive . . . has caused financial harm to my practice by contributing to patients dropping out of my practice." *See* Ex. 16 (Shaw Decl.) ¶ 9.

Dr. Suzanne Berman, a pediatrician in Tennessee and AAP member, operates the only pediatric practice in her county and surrounding counties. *See* Ex. 11 (Berman Decl.) ¶ 11. Dr. Berman stocks the Covid-19 vaccine, and because only the Moderna Covid vaccine is authorized for children six months to 11 years old, she must order the Moderna vaccine for this age group at a cost of $847.10 per dose. *See id*. ¶ 16. The Directive, however, has led to "an increasing number

of parents starting with the presumption or default that their child should not get the Covid-19 vaccine," and has led to a decreasing number of parents consenting to their child getting the Covid-19 vaccine, citing the change to the CDC's immunization schedule as a reason. *Id.* ¶ 17. "The Directive's flipping of the recommendation to SCDM has and will result in continuing financial loss to my clinic" in uncompensated time spent on SCDM counseling and on being unable to return unused doses. *See id*. ¶¶ 17-18.

**ii. The September 19 ACIP Vote**

The ACIP's vote on September 19 that resulted in changing the adult schedule to SCDM for the Covid-19 vaccine has harmed physician members of Plaintiff Organizations. Dr. David Wheeler, member of Plaintiff Infectious Diseases Society of America ("IDSA") and American College of Physicians ("ACP"), attests:

> The recent ACIP recommendation, adopted by the CDC, which shifts the recommendation for Covid-19 vaccines to SCDM for adults under the age of 65, has caused me to spend more time during patient visits discussing the Covid-19 vaccine. There is no billable code that I can use to compensate me for the additional time now spent counseling patients who are resistant to vaccination. Due to this new uncertainty or confusion, on average, I spend about five minutes counseling each patient who is reluctant to receive a vaccine and I may see up to four such patients in a day, so this adds up to 20 minutes per day spent on non-reimbursable vaccine counseling. This is a significant opportunity cost because I could use this time to see an additional patient and get reimbursed for that time.

*See* Ex. 27 (Wheeler Decl.) ¶ 13. Dr. Sindhu Srinivas, President of the Society for Maternal-Fetal Medicine ("SMFM"), attests:

> SMFM members report that counseling patients about Covid-19 vaccination now requires an additional 10–20 minutes per patient, because patients arrive with confusion created by the Directive and ACIP's recent change to the CDC immunization schedule for Covid-19 vaccines to SCDM. The lack of clarity by the ACIP and CDC on what SCDM means for Covid-19 vaccines for pregnant women and the conflict with the Directive has increased consultation time and many SMFM members report not being able to be reimbursed for this increased consultation time, resulting in direct financial losses to SMFM members and their practices. These are quantifiable harms that did not exist prior to the Secretary's Directive, the recommendations approved by the reconstituted ACIP, and the

> CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women.

*See* Ex. 34 (Srinivas Decl.) ¶ 13.

Furthermore, the Directive, the ACIP, and the CDC's "unexplained changes to the CDC immunization schedule for Covid-19 vaccination for pregnant individual[s] … has shifted the burden entirely to individual physicians to defend their medical advice on vaccination …. The deterioration of trust that SMFM physician members are experiencing right now in the exam room with their patients is a direct result of these recent actions by the Secretary, ACIP and CDC." *See* Ex. 34 (Srinivas Decl.) ¶ 15.[5]

The Directive and the ACIP's September 19 vote has also forced Plaintiff Organizations to divert resources to respond to the confusion caused by the policy shift for Covid-19 and other vaccines. SMFM has been "forced to divert substantial time, personnel, and resources away from its regular educational and policy initiatives described above in order to respond to the confusion caused by the policy shift. These efforts have included developing public communications, answering questions from members, correcting misinformation, and coordinating with other national medical associations to reaffirm the evidence-based guidance on Covid-19 vaccination

[5] The declarations submitted by the Plaintiff Organizations and their members (Exs. 2–39) uniformly confirm that the SCDM designation inflicts concrete harm on physicians and public health organizations. *See, e.g.*, Ex. 31 (Bornstein Decl.) ¶¶ 13, 22 ("A question about Covid-19 vaccines might once have taken a few minutes now routinely expands into a 10-minute discussion dominated by the conflict that now exists between my recommendation for Covid-19 vaccination and … the downgrade … to SCDM. These extended counseling sessions are not compensated…."); Ex. 24 (Pavia Decl.) ¶ 28 ("IDSA physicians report … they have been required to spend significantly more unbillable time counseling patients and answering questions from primary care physicians regarding Covid-19 vaccinations. Not only is this time unbillable, but it also infringes on the ability of IDSA physician members to see additional patients and receive reimbursement for that time."); Ex. 19 (Benjamin Decl.) ¶ 21; Ex 12, (Berman Decl.) ¶ 14 ("[M]y colleagues and I are spending increasingly more time counseling patients and their parents and performing work that is uncompensated as a result of the change to SCDM."); Ex 33 (Jaeger Decl.) ¶¶ 6, 8-9 ("SCDM … has shifted responsibility onto parents for understanding the relative risks and benefits of the Covid vaccine … the time necessary to adequately prepare a parent to make a medically sound decision far exceeds what is feasible in a typical 20-minute well child visit … This increased time burden directly harms my ability to provide complete, evidence-based pediatric care."); Ex 26 (Jhaveri Decl.) ¶¶ 11-15 ("The confusion and problems caused by downgrading to SCDM are further compounded by the fact that there is no shared or common understanding of what constitutes 'SCDM' … [and] the cumulative effect of engaging in SCDM with multiple patients every day results in more time spent engaging in work that is not compensable and that detracts from other pressing work.")

during pregnancy. These efforts are essential to mitigate ongoing harm, and they represent a significant and unplanned burden for SMFM." *See* Ex. 34 (Srinivas Decl.) ¶ 17; *see also* Ex. 19, (Benjamin Decl.) ¶¶ 17–29 (detailing harm to both members of the American Public Health Association and to the organization itself due to the Directive and the September 19 vote).[6]

### B. The Secretary's Reconstitution of the ACIP

The Secretary sent further shockwaves through the vaccine ecosystem when he fired all 17 members of the ACIP in a *Wall Street Journal* commentary posted online on June 9, 2025. He justified the terminations with accusations that ACIP members had "persistent conflicts of interest," were "little more than a rubber stamp for any vaccine," and were "directly working for the vaccine industry." *See* TAC, ¶ 49. While his commentary cited reports of conflicts of interest from 1997, 2000, and 2009, none of the 17 terminated members were on the ACIP during those years. *Id* ¶ 50. Moreover, recent research on ACIP conflicts of interest indicated that conflicts were "at historic lows" and "had been virtually eliminated" among recent ACIP membership. *Id*. The Secretary promised that "[b]efore starting work on ACIP, the new members' ethics agreements will be made public." *Id*. To date, the Secretary has not fulfilled his promise.

The ACIP is required by law to have a charter. 5 U.S.C. § 9(c). The ACIP's Charter requires ACIP members to "be knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise

[6] Dr. Benjamin further explains that APHA has ben compelled to divert substantial organizational resources to revise its flagship infectious-disease publications, which are core references relied on my members, including health departments, epidemiologists, and public health practitioners nationwide. *See* Ex. 19 (Benjamin Decl.) ¶¶ 28–29. APHA must now "reconvene editorial contributors, reassess affected chapters, and update guidance to reconcile the scientific evidence with the new CDC immunization schedule recommendations on Covid-19 vaccines," redirecting staff away from ongoing public health priorities. *Id.* The Secretary, ACIP, and CDC's break from the evidence-based process for vaccine recommendations has also weakened APHA's reputation as a reliable conduit of guidance, requiring APHA to expend additional resources to restore confidence in its communications. *See id*.

in assessment of vaccine efficacy and safety." *Id.* ¶ 45. Current ACIP members, however, include a gynecologist, a doctor who has studied myocardial inflammation, a neuroscientist, a professor of operations management, an emergency medicine physician, and a liver transplant doctor. *Id.* ¶ 54. The Federal Advisory Committee Act, 5 U.S.C. §§ 1001, *et seq*. ("FACA"), requires the ACIP to be "fairly balanced" and forbids "inappropriate[] influence[]" by the Secretary. *Id.* ¶ 8. Eight of the Secretary's appointments to the ACIP have publicly stated anti-vaccine views that align with the Secretary's. *See id.* ¶ 55.

## III. ARGUMENT

### A. The Challenge to the Directive Is Not Moot.

A case becomes moot only when "it is impossible for a court to grant any effectual relief whatever to the prevailing party." *Knox v. Serv. Emps. Int' Union, Loc. 1000*, 567 U.S. 298, 307 (2012) (citation modified). As long as any Plaintiff has a concrete interest, "however small, in the outcome of the litigation, the case is not moot." *Id.*; *see also Chafin v. Chafin*, 568 U.S. 165, 172 (2013); *Campbell-Ewald Co. v. Gomez*, 577 U.S. 153, 161 (2016).

In the MTD, Defendants mischaracterize the September 19, 2025 ACIP vote on the Covid-19 vaccine as replacing the Directive. *See* ECF 145, p. 9 ("on October 6, 2025, CDC replaced the immunization schedules from this summer, which had implemented the Directive"). The September 19 ACIP vote did not replace the Directive with respect to the *childhood* schedule, let alone withdraw or rescind the Directive. Only the *adult* schedule changed as a result of that vote, not the childhood schedule. Moreover, even if the Directive were replaced, withdrawn, or rescinded by the September 19 ACIP vote, voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice. *Knox*, 567 U.S. at 307 ("The voluntary cessation of challenged conduct does not ordinarily render a case moot because a dismissal for mootness would permit a resumption of the challenged conduct as soon as the case

is dismissed."); *see also Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc*., 528 U.S. 167, 189 (2000).

In order for a case to be moot, intervening events must "have completely and irrevocably eradicated the effects of the parties' conduct in order for a case to be deemed moot." *Town of Barnstable v. O' Connor,* 786 F.3d 130, 142 (1st Cir. 2015) (citation modified) (quoting *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979)). Before the September 19 ACIP vote, only the childhood schedule, which is applicable to those six months to 17 years old, designated the Covid-19 vaccine as SCDM per the Directive. The September 19 vote expanded the population of those covered by the SCDM designation for the Covid-19 vaccine from those under 18 to everyone under the age of 65. Plaintiffs have submitted scores of declarations attesting to the harm that the change from a routine recommendation to SCDM caused the Plaintiffs. Thus, far from eradicating the effects of the Directive, the September 19 ACIP vote to designate the Covid-19 vaccine as SCDM for everyone under 65 perpetuated and increased the harm that the Directive caused during the preceding four months. Moreover, neither the ACIP nor CDC have explained whether the September 19 vote superseded the Directive's command to the CDC to remove the recommendation that pregnant women receive the Covid-19 vaccine or whether the Directive's instruction regarding pregnant women remains in force. *See* Ex. 34 (Srinivas Decl.) ¶ 13 (noting that the SCDM designation for individuals six months through age 64 "conflict[s] with the Directive."). The Defendants' mootness argument is wholly without merit.

### B. The Plaintiff Medical and Public Health Associations Have Established Organizational Standing.

Organizational standing exists when the challenged conduct causes "'concrete and demonstrable injury to the organization's activities' together with a 'consequent drain on the organization's resources' that is 'more than simply a setback to the organizations' abstract social

interests.'" *Am. Ass'n of Univ. Professors v. Rubio*, 780 F.Supp.3d 350, 379 (D. Mass. 2025) (quoting *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982)). In the First Circuit, "[i]t is a bedrock proposition that a relatively small economic loss – even an identifiable trifle – is enough to confer standing." *Massachusetts v. U.S. Dep't of Health and Hum. Servs.*, 923 F.3d 209, 222 (1st Cir. 2019) (citation modified). Thus, if a plaintiff's core service is "perceptibly impaired by the defendant's actions," organizational standing is satisfied. *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982). In *Havens*, as described by the Supreme Court in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367, 395 (2024), the "[defendant] gave [plaintiff's] employees false information, … [which] directly affected and interfered with [plaintiff's] core business activities." Thus, in *Havens*, the plaintiff established standing because of the direct interference with the plaintiff's core business activities, whereas in *Hippocratic Medicine*, plaintiffs did not establish organizational standing because they did not allege "any similar impediment" to their core business activities. *Havens*, 455 U.S. at 379; *Hippocratic Medicine*, 602 U.S. at 395.

This case aligns squarely with *Havens*, whereas *Hippocratic Medicine* is clearly distinguishable.[7] While each of the Plaintiff Organizations in this case serve different populations, a mission common to all of the Plaintiff Organizations in this case is to enhance the quality and effectiveness of health care services in this country and to assist and support their members' delivery of health care services consistent with the applicable standard of care. The actions

[7] In *Hippocratic Medicine*, 602 U.S. at 372-73, anti-abortion doctors and their medical associations challenged the FDA's relaxing of restrictions on the prescribing of mifepristone, a drug used to terminate pregnancies up to seven weeks. The plaintiff doctors and medical associations themselves did not prescribe mifepristone, and federal conscience laws protected them from being forced to do so. *Id.* at 387. Thus, their objection to the FDA's action was an objection to mifepristone being prescribed *by others*. *Id.* at 388-89. The Supreme Court held that the plaintiff medical associations could not establish organizational standing simply because they incurred costs to object to an action that they objected to on ideological grounds but that did not impair their core business activities. *Id.* at 395 (an organization "cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action" based on moral objections to an action that did not impose "any similar impediment to the medical associations' advocacy business.").

challenged here—the Directive, the packing of the ACIP with vaccine skeptics and deniers, and the ACIP's September 19 vote to designate the Covid-19 vaccine SCDM for everyone under 65—all fundamentally and directly interfere with this mission. As Dr. Srinivas, President of SMFM declares, the "Directive has directly impacted SMFM physician members' ability to provide the optimal standard of care," because Directive the overrides "their clinical judgment, which is rooted in years of medical training, board certification in maternal-fetal medicine, and reliance on data from peer-reviewed literature and prior CDC/ACIP recommendations ...." *See* Ex. 34 (Srinivas Decl.) ¶ 11. Dr. Benjamin, Executive Director of the APHA, declares that the challenged actions have eroded public trust in APHA members and led to the questioning of APHA members' professional competence and integrity, which "directly impair the APHA members' ability to protect their communities—one of their core professional duties." *See* Ex. 19 (Benjamin Decl.) ¶ 20. Because of the direct impact the challenged actions have had on AAP's core mission, Plaintiff AAP has been "forced [at] all levels of the AAP to divert significant time away from other tasks and initiatives related to child health … to attempt to clear up the confusion and diminish the chaos the Directive has, unfortunately and unnecessarily, generated." *See* Ex 15 (Del Monte Decl.) ¶ 9.[8]

The initiatives that Plaintiff Organizations have had to take to address the fallout from the challenged actions are not, as Defendants mischaracterize, "a continuation of [the organizations'] 'ongoing activities.'" Indeed, Plaintiff Organizations would not be undertaking these new activities and initiatives to combat Covid-19 vaccine and other misinformation but for the Secretary's actions challenged here. There is no legitimate question that Plaintiffs have organizational standing. *See Diamond Alt. Energy, LLC v. EPA*, 606 U.S. 100, 113 (2025).

[8] Indeed, each Plaintiff Organization and its members have been forced to redirect considerable time and resources to responding to the confusion and disruption stemming from the SCDM recommendation for the Covid-19 vaccine. *See* Ex. 17 (Goldman Decl.) ¶ 11; Ex. 19 (Benjamin Decl.) ¶¶ 25-30; Ex. 24 (Pavia Decl.) ¶¶ 22-24, 26, 28; Ex. 25 (LaRocque Decl.) ¶¶ 16-19; Ex. 32 (Pavlos Decl.) ¶¶ 17, 20-23; Ex. 34 (Srinivas Decl.) ¶¶ 10, 16-18, 22.

### C. The Plaintiff Medical and Public Health Associations Have Established Associational Standing.

Associational standing is established here because the doctors who have submitted declarations in this case unquestionably could sue in their own right. First, the doctor-declarants have suffered financial injury, including engaging in SCDM conversations without compensation, absorbing the full cost of purchasing vaccine doses that go unused due to the Directive's suppression of vaccine uptake, and being able to see fewer patients per day due to the increased amount of time spent with patients discussing vaccines.[9] These financial losses are more than a trifle, and "a relatively small economic loss – even an identifiable trifle – is enough to confer standing." *Massachusetts v. U.S. Dep't of Health and Hum. Servs.*, 923 F.3d 209, 222 (1st Cir. 2019) (citation modified). Second, the final agency actions challenged here have interfered with physicians and their practice's ability to do their jobs, which alone is sufficient to establish standing.[10] *See Havens,* 455 U.S. at 379 (where defendants' racially discriminatory steering

[9] *See, e.g.*, Ex. 6 (O'Shea Decl.) ¶¶ 8, 10–11 ("I have had to dedicate time and resources to developing a plan for complying with the SCDM requirement … [t]his has caused a direct financial impact on my practices, as none of that time I've spent developing these plans and protocols is reimbursable or billable…My practices have also had to forego our annual flu and Covid-19 vaccination clinics as a result of the CDC's downgrade of the Covid-19 vaccine recommendation for children…to SCDM."); Ex. 8 (Scott-Vernaglia Decl.) ¶¶ 17, Ex. 10 (Boyce Decl.) ¶ 13; Ex. 11 (Berman Decl.) ¶¶ 15–16, 19 (likely not to be reimbursed or to be able to return vaccine doses that cost $104.54/dose or $847/dose); Ex. 12 (Berman Supp. Decl.) ¶¶ 14–16; Ex. 13 (Andreae Decl.) ¶ 14 ("losing about $150/day" in uncompensated time because of "vaccine refusal rates tied to the Directive"); Ex. 14 (Andrae Supp. Decl.) ¶ 18 ("SCDM conversations forces me and my colleagues to devote substantial work time after office hours to complete documentation or other tasks not completed during or between wellness visits … SCDM is causing more and more work to be performed without compensation resulting in … lost earnings."); Ex. 7 (Shaw Decl.) ¶¶ 7–8; Ex. 17 (Goldman Decl.) ¶ 11; Ex. 18 (Hopkins Decl.) ¶¶ 25, 36 ("There is no payment for vaccine counseling which does not result in a vaccine being administered, which accounts for approximately 20–25% of the SCDM conversations in my practice."); Ex. 24 (Pavia Decl.) ¶¶ 26, 28; Ex. 25 (LaRocque Decl.) ¶ 17; Ex. 26 (Jhaveri Decl.) ¶¶ 13, 15 ("SCDM discussion that takes 10 or even 20 minutes is 10 or 20 minutes of time that is not reimbursed and that accumulates into hours additional work…."); Ex. 27 (Wheeler Decl.) ¶¶ 11–15; Ex. 28 (Chen Decl.) ¶ 20; Ex. 31 (Bornstein Decl.) ¶¶ 13–14; 24–25; Ex. 33 (Jaeger Decl.) ¶¶ 8–9; Ex. 36 (Ramsey Decl.) ¶¶ 7, 10, 12–17.

[10] *See, e.g.*, Ex. 10 (Boyce Decl.) ¶ 9; Ex. 14 (Andreae Supp. Decl.) ¶ 19; Ex. 7 (Shaw Decl.) ¶ 7; Ex. 24 (Pavia Decl.) ¶ 23; Ex. 25 (LaRocque Decl.) ¶ 18; Ex. 26 (Jhaveri Decl.) ¶¶ 11, 14–15 ("[T]he quality and quantity of time spent on issues at the core of the wellness visit suffer because of the downgrading of the Covid-19 vaccine from routinely recommended to SCDM."); Ex. 27 (Wheeler Decl.) ¶¶ 8–9, 11, 14, 16 ("ACIP, supported by the CDC staff—function as the brain of the system … [and] [c]ommunity infectious disease physicians like me serve as the arms and fingers of that system. Our role as physicians is to take … evidence-based recommendations from ACIP and the CDC and implement them in the real world …. ACIP did not provide me with the guidance I need to understand the change and apply it. This has further complicated my counseling process with patients and providers who ask me

practices "have perceptibly impaired [plaintiff's] ability to provide counseling and referral services for low- and moderate-income homeseekers, there can be no question that the [plaintiff] has suffered injury in fact"). Third, the Secretary's threat of legal liability for administering vaccines contrary to CDC guidance also demonstrates sufficient harm.[11] *See 303 Creative LLC v. Elenis*, 600 U.S. 570, 597 (2023) (wedding website designer who preemptively proclaimed she would not design a website for a same-sex couple had standing even though no same-sex couple had tried to engage her services because a credible threat of legal consequences existed).[12]

To answer Justice Scalia's famous question—"What's it to you?"—doctors in this case have a "personal stake" in not suffering financial loss, in being able to practice medicine consistent with their applicable standard of care,[13] in not being sued, and in keeping their license to practice medicine, all of which are directly affected by the change of the Covid-19 vaccine routine recommendation to an SCDM designation. Contrary to Defendants' assertions, these injuries are not too attenuated from the challenged actions or too speculative to be actionable but instead are directly in the causal chain from action to injury.

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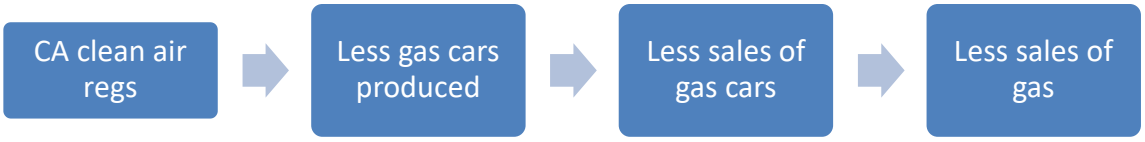
for guidance on the Covid-19 vaccine…."); Ex. 28 (Chen Decl.) ¶¶ 18–22 ("SCDM is like adding a ten-page consent form to a ferris wheel ride that has always been safe, creating doubt and uncertainty where none previously existed, which adds time to the physician-patient counseling discussions to overcome new mistrust."); Ex. 30 (Pring Decl.) ¶ 25; Ex. 31(Bornstein Decl.) ¶¶ 10, 12, 20–23; Ex. 33 (Jaeger Decl.) ¶¶ 7, 14 ("The Directive and recent actions by the ACIP and CDC are interfering with my ability to provide the standard of care…."); Ex. 35 (Rouse Decl.) ¶¶ 11; Ex. 36 (Ramsey Decl.) ¶ 10–14, 17.

[11] On the same day that the AAP issued its own evidence-based immunization schedule, the Secretary posted on X that "AAP today released its own list of corporate-friendly vaccine recommendations … AAP should also be candid with doctors and hospitals that recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act." *See* TAC, ¶ 86.

[12] Physicians also report that the Secretary, ACIP, and CDC's changes to the CDC immunization schedule for Covid-19 vaccination expose them to liability. *See, e.g.*, Ex. 14 (Andreae Decl.) ¶ 20; Ex. 33 (Jaeger Decl.) ¶ 14 ("[B]y following … professional guidelines I know that I am now potentially placing myself at odds with the federal directive. I am exposing myself to malpractice liability, jeopardizing my medical license, and facing disciplinary action ….")

[13] *See Cain v. Niemela*, 2020 WL 4249161, at *6 (Mich. Ct. App. July 23, 2020) ("A plaintiff in a medical malpractice action must establish, among other elements, the applicable standard of care governing the defendant doctor's actions and that the defendant doctor breached that standard." (citation modified) (quoting *Elher v. Misra*, 878 N.W.2d 790, 795 (Mich. 2016)); *Palandjian v. Foster*, 842 N.E.2d 916, 920 (Mass. 2006) ("To prevail on a claim of medical malpractice, a plaintiff must establish the applicable standard of care and demonstrate both that a defendant physician breached that standard, and that this breach caused the patient's harm.").

The Supreme Court's recent *Diamond Alternative Energy* decision is on all fours with this case. There, the plaintiffs, gasoline producers, alleged the following chain of causation from California clear air regulations aimed at reducing carbon emissions to their injury:




*See Diamond Alt. Energy*, 606 U.S. at 105. The gas producers' theory of causation and redress thus depended on the actions of multiple third parties, *i.e.*, "without California's regulations in effect, manufacturers would likely make more cars powered by gasoline and other liquid fuels, thereby increasing purchases of those fuels and redressing the fuel producers' injury." *Id*. The Supreme Court held this chain of causation sufficient to confer standing because "a court must conclude that third parties will likely react to the government regulation … in predictable ways that will likely cause (or redress) the plaintiff's injury." *Id.* at 112 (citation modified); *see also Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 155 (2010) (FDA's deregulation of genetically-engineered alfalfa seed created a "reasonable probability" of contamination of organic or conventional alfalfa crops that, in turn, created a need for organic farmers to test their crops for contamination, an expense they previously had not incurred. "Such harms, which respondents will suffer even if their crops are not actually infected with the [genetically-engineered] gene, are sufficiently concrete to satisfy the injury-in-fact prong of the constitutional standing analysis" and were "readily attributable to [the] deregulation decision.").

Here, as in *Diamond Alternative Energy* and *Monsanto,* patients have indeed reacted predictably to the false information that the Secretary has spread about the Covid-19 vaccine—they have believed or credited the statements of this country's highest-ranking health official—which has impaired the ability of doctors to practice medicine consistent with the standard of care

and has caused them financial loss. This is injury in fact, and the Plaintiffs have established associational standing.

**D. The Individual Plaintiffs Have Standing**

All three individual plaintiffs have suffered concrete injuries traceable to the Directive and related changes to the CDC vaccination schedule, which are redressable by this Court. These injuries include loss of access to the Covid vaccine, physical harms, financial harms, and lost time spent navigating the confusion that directly resulted from these policy changes. *See TransUnion, LLC v. Ramirez*, 594 U.S. 413, 425 (2021) ("[C]ertain harms readily qualify as concrete injuries under Article III. … If a defendant has caused physical or monetary injury to the plaintiff, the plaintiff has suffered a concrete injury in fact under Article III."); *Tignor v. Dollar Energy Fund, Inc.*, 745 F.Supp.3d 189, 201 (W.D. Pa. 2024) (fear, anxiety, and stress were sufficient, concrete injuries).

**E. Count II States a Plausible Claim for Relief Under the Administrative Procedure Act.**

The First Circuit's decision in *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 20 (1st Cir. 2020) is dispositive of Defendants' 12(b)(6) motion on this count. There, the First Circuit reversed the district court's dismissal of the plaintiffs' claims that an EPA federal advisory committee was not fairly balanced and was inappropriately influenced by the appointing official in violation of FACA. The First Circuit noted that while FACA contains no private right of action, the APA "generally provides a vehicle for reviewing agency decisions that are alleged to violate federal law." *Union of Concerned Scientists*, 954 F.3d at 17. The court then held that:

> FACA requires EPA to maintain a fair balance on its committees and to avoid inappropriate influences by both the appointing authority and any special interest. Plaintiffs allege that the directive skewed the composition of EPA committees in favor of regulated industries. They further allege that the EPA offered no rational reason for finding that any benefits of the policy justified the alteration of balance and influence on the committees. Indeed, the allegation is that the EPA did not even

> acknowledge that the directive had such an effect.[14] These allegations plausibly state claims for judicial review under the APA.

*Id.*

*Union of Concerned Scientists* compels the denial of Defendants' 12(b)(6) motion to dismiss Count II. Count II states a plausible claim that the Secretary violated FACA with his appointments of the current members of the ACIP and that he has inappropriately influenced the current ACIP. *See* TAC, ¶¶ 46–56, 73–82. The following undisputed sequence of events indicates that the Secretary rigged the ACIP in violation of FACA and the APA to further his vaccine policy goals:

| | |
|---|---|
| June 9, 2025 | Secretary fires all 17 members of the ACIP.[15] |
| June 11, 2025 | Secretary announces the appointment of eight new members to the ACIP.[16] |
| August 27, 2025 | Secretary fires Susan Monarez, CDC Director.[17] |
| August 29, 2025 | Secretary appoints Jim O'Neill Acting CDC Director.[18] |
| September 11, 2025 | Secretary announces the appointment of four new ACIP members.[19] |
| September 17, 2025 | Monarez testifies before the Senate Finance Committee that the Secretary "directed me to commit in advance to approving every ACIP recommendation, regardless of the scientific evidence."[20] |
| September 19, 2025 | ACIP votes in favor of SCDM for the Covid-19 vaccine for everyone under 65.[21] |

[14] The directive at issue in *Union of Concerned Scientists* was one that "disqualifie[d] thousands of scientists [who were grant recipients] affiliated with academic and not-for-profit institutions. And precisely because those scientists … tend to be leaders in their fields, the directive is said to target many of the most knowledgeable scientists who are not affiliated with industry. … As a result, the plaintiffs allege that the directive has quickly and materially increased the participation of industry-affiliated scientists on EPA committees." *Union of Concerned Scientists*, 954 F.3d at 15.

[15] *See* TAC ¶¶ 46–48.

[16] *Id.* ¶ 53.

[17] *Id.* ¶ 72.

[18] *See* Emily Anthes, *Who Is the New Acting C.D.C. Director?*, N.Y. TIMES (Aug. 29, 2025), https://www.nytimes.com/2025/08/29/health/james-oneill-cdc.html? [https://perma.cc/W48U-TDGE] ("The pick leaves the nation's premier public health agency under the leadership of an official without medical or scientific training.").

[19] *See* TAC ¶¶ 53–54.

[20] *See Restoring Trust Through Radical Transparency: Reviewing Recent Events at the Centers for Disease Control and Prevention and Implications for Children's Health*, Senate HELP Committee Hearing (Sept. 17, 2025), https://www.help.senate.gov/imo/media/doc/e7a31f2a-d31c-42bb-1a9538e6abef8195/Monarez%20Testimony.pdf

[21] *See* TAC ¶¶ 73–75.

| | |
|---|---|
| October 6, 2025 | O'Neill endorses the ACIP's September 19 vote.[22] |

These facts state a plausible claim that the Secretary's reconstitution of the ACIP violated FACA's "fairly balanced" and "inappropriately influence" provisions and, therefore, violated the APA. Plaintiffs should be allowed to move forward on this claim. *See Union of Concerned Scientists*, 954 F.3d at 22 (allowing plaintiffs to move forward on their claim that "the challenged EPA action was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law precisely because the EPA failed to rationally consider and explain the effects of the directive under FACA's standards.").

The First Circuit also blessed the type of relief that Plaintiffs seek here. The court noted that if plaintiffs "are successful and the EPA is forced to abandon the directive, grant recipients will again be permitted to sit on the EPA's committees. So long as there is some concrete interest, however small, in the outcome … the case is not moot." *Union of Concerned Scientists*, 954 F.3d at 22-23 (citation modified); *see also Nat'l Ass'n of Consumer Advocs., et al. v. Uejio,* 521 F.Supp.3d 130, 144–46 (D. Mass. 2021) (plaintiffs had standing to challenge composition of Federal Consumer Financial Law Taskforce, and if plaintiffs proved on the merits that Taskforce violated FACA requirements, then plaintiffs were entitled to a declaration that Taskforce and all of its actions could be set aside and Taskforce could be enjoined from meeting or conducting any business).

## IV. CONCLUSION

Based on the foregoing facts, arguments, and authorities, Defendants' Motion to Dismiss should be denied in its entirety.

[22] *See id.* ¶ 7.

Dated: December 3, 2025

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that this document was filed through the the Court's CM/ECF System on this 3rd day of December 2025 which will send notification to the following parties:

Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services

Jim O'Neill, in his official capacity as Acting Director of the Centers for Disease Control and Prevention

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